REMARKS

Priority

The Office Action stated that the applicant has not complied with one or more conditions to receiving the benefit of an earlier filing date under 35 U.S.C. § 120. Specifically, the Office Action stated that the application failed to state the relationship to the prior nonprovisional application in the first sentence of the application. Applicants' amendment to the specification includes this relationship. Accordingly, Applicants request confirmation that this application now complies with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120.

35 U.S. C. § 103(a)

Claims 1-53, 80-121, and 137-231 have been rejected under 35 U.S. C. § 103(a) as being unpatentable over Grass (reference BW in the Information Disclosure Statement filed July 17, 2001) in view of Gex-Fabry et al. (reference BT in the Information Disclosure Statement filed July 17, 2001). Specifically, the Patent Office states:

> It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method and computer models of Grass et al. [sic] by refining the parameters used in the model by use of data from a plurality of compounds because Gex-Fabry et al. shows such refinement is useful to obtain more accurate parameters.

Applicants respectfully disagree and traverse this rejection. The claimed invention provides methods and systems whereby pharmacokinetic data from one location (or animal) can be used to predict oral absorption in another location (or animal). This is accomplished by performing calculations that use "adjustment parameter values" and/or "regional correlation coefficients" (a type of adjustment parameter). These values are estimated by comparing the data from many compounds in, for example, a first and second organ. From the compared data, estimates can be made for a coefficient or adjustment parameter which can be used to make a prediction from known data in one organ to unknown results in a second organ. These parameters help the user of the invention predict absorption from a first location to second location. There are commonalities of going from, for example, a dog's stomach to a human colon or the like and these can be captured by parameters in equations and used in the models, with the result being a better choice of which compounds to explore further. The adjustment

parameters can be real or abstract and can describe the relationship between unknown factors in the model, thus making the model predict more accurately.

The adjustment parameters are unique to the model in the claimed invention and are not taught in Grass or Gex-Fabry. The adjustment parameters being optimized in this application do not exist in Grass.

The Patent Office concedes that Grass does not teach "fitting of pharmacokinetic data of multiple compounds to derive parameters for use in the model" for the invention in this application. The Office Action says it is obvious to refine parameters in the model of this invention by the use of data from a plurality of compounds.

The applicant respectfully disagrees. First of all, Gex-Fabry does not teach the use of multiple compounds to refine parameters. Even more important to the nonobviousness of the claimed invention is the concept of what parameters are being refined. The cited Grass reference teaches elements of the invention but does not teach the regional correlation coefficient or the adjustment paramenter. Gex-Fabry teaches estimating parameters in general, but which parameters? One would need to have a parameter in mind in order to refine it by the methods of Gex-Fabry. There is no teaching or suggestion of the regional correlation coefficient or the adjustment parameter in either reference. It would not be obvious to a person of ordinary skill in the art to move from Grass, where no parameter refinement was necessary, to conceptualizing one or more new parameters to add to the model to account for relationships between unknown factors.

Gex-Fabry teaches a variety of error correction and parameter estimation methods. But Gex-Fabry does not correct the deficiencies of the missing elements in Grass, the regional correlation coefficient and the adjustment parameter.

Claims 2-21, 22, 50-53, 82, 105-121, 147, 181, 183-197, and 199-215 contain the element of regional correlation coefficient/estimation/parameter. Claims 1, 22-53, 80-104, 121, 137-158, 159-181, 182-183, 195, 197-198, 216-231 contain the element of adjustment parameter/value. Accordingly, Grass together with Gex-Fabry fails to teach and/or suggest each and every element of the claimed invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-53, 80-121, and 137-231.

Summary

In light of the above amendment and remarks, consideration of the subject patent application is respectfully requested.

Respectfully submitted,

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Date: 6|30|06